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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:	Samir F. Saba		
Serial No.:	10/535,529	Art Unit:	3762
Filed:	05/09/2006	Examiner:	Evanisko, G.
Entitled:	**A Device And Method to Discriminate Between Supraventricular Tachycardias And Ventricular Arrhythmias**		

RESPONSE TO PROVOKE AN ADVISORY ACTION IN REPLY TO FINAL OFFICE ACTION MAILED MAY 27, 2010

Mail Stop - Amendments
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Examiner Evanisko:

Please enter the following on the record in response to the above-cited Final Office Action mailed May 27, 2010. This response is intended to provoke an Advisory Action mailed within two months of the mailing date of the Final Office Action.

The Examiner is requested to note that the amendments provided herein have already been searched such that a Request For Continued Examination is not required. For example, the Applicants respectfully point out that, as a National Phase Entry application of PCT/2003/037099, original Claims 16, 17, 23, and 24 recite "ventricular tachycardia" or "supraventricular tachycardia" in the context of identifying the cardiac origin based upon an earliest arriving electrical signal. The International Search Report (mailed Nov 18, 2004) included searches of original Claims 16, 17, 23, and 24. In fact, the search terms used were "atria, ventricle, simultaneous, pacing, defibrillating, AV, tachycardia, and ECG. This search identified two US patents: i) 5,383,910 To den Dulk, and ii) 5,476,482 To Lu. Neither, patent discloses discriminating "ventricular tachycardia" from "supraventricular tachycardia" in the context of identifying the cardiac origin based upon an earliest arriving electrical signal (*infra*).

Further, the parent application (now issued as US Pat No 7,206,633) recite "ventricular tachycardia" and/or "supraventricular tachycardia" in issued Claims 5, 6, 13, and 14 in the context of identifying the cardiac origin based upon an earliest arriving electrical signal. Clearly, these claims were searched and found patentable.

Beginning on page 3 of this communication, please find a status of all claims with instructions for entry pursuant to 37 CFR §1.21. Applicants' remarks regarding the claims and the Office Action begin on page 4.

Amendments To The Claims

1-5. (Canceled)

6. (Withdrawn) A method, comprising:

a) providing:

i) a patient implanted with a device, wherein said device comprises;

1) a implantable pacemaker element; and

2) a plurality of atrial and ventricular pacing leads connected to said pacemaker element, wherein said pacing leads are configured for simultaneous activation and coursing to the ventricles and atria; and

ii) a plurality of sensing leads connected to said pacemaker coursing to the ventricles and atria;

b) initiating one or more pacing bursts by said pacemaker element, wherein said ventricles and atria are simultaneously paced; and

c) detecting an earliest arriving electrical signal following termination of said pacing bursts.

7. (Withdrawn) The method of Claim 6, wherein prior to step b) a cardiac arrhythmia is detected in said patient.

8. (Withdrawn) The method of Claim 6, wherein said earliest arriving electrical signal is from the ventricles.

9. (Withdrawn) The method of Claim 6, wherein said earliest arriving electrical signal is from the atria.

10. (Withdrawn) The method of Claim 6, further comprising step d) defibrillating said ventricles under conditions such that normal sinus rhythm is restored.

11-26. (Canceled)

27. (Currently Amended) A device, comprising:

~~a)~~ an implantable pacemaker further comprising an atrial lead and a ventricular lead, said atrial lead and said ventricular lead further comprising distal tip electrodes configured to deliver simultaneous anti-tachycardia pacing bursts and wherein said device is configured to discriminate between a supraventricular tachycardia and a ventricular tachycardia by determining if ~~detect~~ an earliest arriving electrical signal was detected by said atrial lead distal tip electrodes or said ventricular lead distal tip electrodes following ~~a blanking period resulting from~~ said pacing bursts[[;]]

~~b) an implantable cardiac defibrillator attached to said pacemaker; and~~

~~c) a timing device connected to said pacemaker, said timing device configured to identify the origin of an arrhythmia by determining if said earliest arriving electrical signal was detected by said atrial lead distal tip electrodes or said ventricular lead distal tip electrodes.~~

28. (Previously Presented) The device of Claim 27, wherein said pacemaker further comprises a microprocessor configured to initiate said pacing burst.

29. (Previously Presented) The device of Claim 27, wherein said pacemaker generates said anti-tachycardia pacing burst.

30. (Canceled)

31. (Previously Presented) The device of Claim 27, wherein said atrial lead and said ventricular lead further comprise defibrillation electrodes.

32. (Canceled)

33. (Previously Presented) The device of Claim 27, wherein said pacemaker further comprises a storage memory connected to said atrial and ventricular leads.

34. (Previously Presented) The device of Claim 31, wherein at least one of said defibrillation electrodes is configured to convert an abnormal heart rhythm into normal sinus rhythm.

35. (Previously Presented) The device of Claim 27, wherein said atrial lead and said ventricular lead are quadripolar.

36. (Previously Presented) The method of claim 27, wherein said atrial lead and said ventricular lead further comprise separate conductors.

37. (Currently Amended) A device, comprising:

~~a)~~ an implantable pacemaker further comprising at least one atrial lead and at least one ventricular lead, said at least one atrial lead and said at least one ventricular lead further comprising distal tip electrodes configured to deliver simultaneous anti-tachycardia pacing bursts and wherein said device is configured to discriminate between a supraventricular tachycardia and a ventricular tachycardia by determining if ~~detect~~ an earliest arriving electrical signal was detected by said atrial lead distal tip electrodes or said ventricular lead distal tip electrodes following ~~a blanking period resulting from~~ said pacing bursts[[;]]

~~b) an implantable cardiac defibrillator attached to said pacemaker; and~~

~~c) a timing device connected to said pacemaker, said timing device configured to identify the origin of an arrhythmia by determining if said earliest arriving electrical signal was detected by said at least one atrial lead distal tip electrode or said at least one ventricular lead distal tip electrode~~.

38. (Previously Presented) The device of Claim 37, wherein said pacemaker further comprises a microprocessor configured to initiate said pacing burst.

39. (Previously Presented) The device of Claim 37, wherein said pacemaker generates said anti-tachycardia pacing burst.

40. (Previously Presented) The device of Claim 37, wherein said at least one atrial lead and said at least one ventricular lead further comprise defibrillation electrodes.

41. (Previously Presented) The device of Claim 37, wherein said pacemaker further comprises a storage memory connected to said atrial and ventricular leads.

42. (Canceled)

43. (Previously Presented) The device of Claim 37, wherein said at least one atrial lead and said at least one ventricular lead are quadripolar.

44. (Previously Presented) The method of claim 37, wherein said at least one atrial lead and said at least one ventricular lead further comprise separate conductors.

REMARKS

The Examiner provides a number of restrictions and rejections; we list them here in the order in which they are addressed.

I. Claims 27-29, 31 and 33-44 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

II. Claims 27-29, 31, 33, 34, 36-42 and 44 are rejected under 35 U.S.C. §102(e) as allegedly being anticipated by Kupper *et al.*

III. Claims 35 and 43 are rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Kupper *et al.*

I. The Claims Comply With The Written Description Requirement

The Examiner states that:

> The subject matter which was not described in the original specification was a "timing device configured to identify the origin of an arrhythmia" ... The original specification on page 11, line 21 is the only place that "timing device" is mentioned ... but is not mentioned to be "configured to identify the origin of an arrhythmia".

Office Action pg. 3. The Applicants disagree. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claims 27 and 37 to delete the "timing device" claim term. Further, Claims 27 and 37 are clarified by removing the unnecessary claim term "implantable cardiac defibrillator". These amendments are made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application.

The Examiner is respectfully requested to withdraw the present rejection.

II. The Claims Are Novel

The Examiner states that:

> Kupper discloses a pacemaker/defibrillator ... [that] ... necessarily does determine the earliest arriving electrical signal and the location of origin (atrium or ventricle) ... since following therapy it waits to sense a ventricular or atrial event ...

Office Action pg 3 bridging pg 4. The Applicants disagree as Kupper does not teach determining the origin of an arrhythmia based upon the determination of the earliest arriving signal. Nonetheless, without acquiescing to the Examiner's argument but to further the prosecution, and hereby expressly reserving the right to prosecute the original (or similar) claims, Applicants have amended Claims 27 and 37 to clarify that the pacemaker ..."is configured to discriminate between a supraventricular tachycardia and a ventricular tachycardia ...":

> The present invention contemplates a novel capability that detects an earliest arriving electrical signal (i.e., an intracardic electrogram) that discriminates between supraventricular tachycardia (SVT) and ventricular tachycardia (VT).

Applicant's Specification pg 2 ln 28-30. This amendment is made not to acquiesce to the Examiner's argument but only to further the Applicants' business interests, better define one embodiment and expedite the prosecution of this application. The Examiner should note that Claims 27 and 37 are further redrafted by incorporating the phrase "detected by said atrial distal tip electrodes or said ventricular distal tip electrodes" that was removed from step c).

As argued above, the Examiner is respectfully requested to note that the concept of "discriminating between a supraventricular tachycardia and a ventricular tachycardia by determining if an earliest arriving electrical signal was detected ..." was completely

searched because they are: i) recited in issued claims from the parent application; and ii) were searched in the International Search Report (ISR) under the instant PCT application (*supra*). In particular, the ISR identified two patents of relevance, neither of which anticipate, or make obvious, the currently amended claims.

In regards to US Patent No. 5,838,910, this technology discloses a device that is configured to measure the intervals between atrial depolarizations and ventricle depolarizations during a tachycardia in order to distinguish re-entrant nodal tachycardia from sinus tachycardia. The '910 patent does not describe a device configured to detect an earliest arriving electrical signal to determine the whether the cardiac origin of the tachycardia is from the atria or from the ventricle.

In regards to US Patent No. 5,476,482, this technology discloses a stand-alone computer that receives telemetered pacemaker data in order to determine whether retrograde conduction is occurring in the patient. The '482 patent does not describe a device configured to detect an earliest arriving electrical signal to determine the whether the origin of the tachycardia is from the atria or from the ventricle.

In conclusion, the Applicant submits that the claim terms of discriminating between "supraventricular tachycardia" and/or "ventricular tachycardia" in the context of determining the earliest arriving electrical signal has been fully searched and is on the record of the instant application.

Consequently, the Applicants respectfully request that the Examiner withdraw the pending rejection and allow the claims as an Advisory Action, such that a Request For Continued Examination is not required.

III. Claims 35 and 43 Are Not Obvious Over Kupper

The Examiner states that:

> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD as taught by Kupper …

Office Action pg 4 bridging pg 5. The Applicants disagree because the Examiner is referring to dependent claims. Because the respective independent claims (i.e., Claims 27

and 37, respectively) have not been rejected as obvious, the dependent claims are non-obvious as well:

> Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.

In re Fine, 837 F.2d 1071, 1076, 5 USPQ2d 1596 (Fed. Cir. 1988). Consequently, the Applicants respectfully requests that the Examiner withdraw the present rejection.

CONCLUSION

Based on the arguments provided above, Applicants believe that the Claims 27-29, 31 and 33-44 are in condition for allowance. Should the Examiner believe a telephone interview would aid in the prosecution of this application, the Applicants encourage the Examiner to call the undersigned at 781-828-9870.

Respectfully submitted,

Dated: July 22, 2010

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